Food and Drug Administration Office of Regulatory Affairs

Summary Report

For Sample Number: 764940 13206132

TD Sample Number: **Import Sample Number**

This is an accurate reproduction of the original electronic record as of 12/10/2012

Sample Class: Normal Everyday Sample
Sample Origin: Domestic
Sample Basis: Other-Compl
Sample Flag:
Sample Type: Official
Collecting District: NOL-DO
Home District:
Orig C/R and Records To: NOL-DO
Collection PACs: 56R814

Product Name: Methylprednisolone Acetate (Glucocorticoid); Human - Rx/Combination Ingredient; Sterile Liquid

Product Description: Methylprednisolone Acetate 80mg/ml packaged in 1ml clear glass vials. (Cont in Remarks)

Collection Reason: Collected during investigation of Aspergillus Meningitis outbreak. Analyze for sterility (presence of Aspergillus) and chemical composition.

Lab: NRL **Split Num:** 0 **Date Received:** 10/05/2012 **Date Out of Lab:** 12/10/2012

District Conclusion: **District Conclusion Made By:** **District**

Disposition Reason: **Disposition Authorized By:** **Disposition Authorized Date:**

NWE DISTRICT OFFICE 2012 DEC 19 PM 12 35

Performing Org	PAC	LID	PAF	Compliance No	Lab Class-Description	Laboratory Status
NRL-MSB-K	56R814	M	NAR		3 - Adverse Findings	Completed

Lab Conclusion

Viable microorganisms detected in forty eight (48) of seventy eight (78) units examined.
Yeast-like organisms detected in units # 3, 4, 6, 7, 8, 10, 13, 28E, 29A, 29D, 30A, 30D, 30E, 31B, 31D, 32B, 33A, 33B, 34C, 35A, 35E, 36D, 37B, 38B, 38C ,38D, 38E and 40E.
Yeast-like and mold-like organisms detected in units # 12, 28A, 28B, 28D, 29C, 30C, 31C, 32A, 32C, 32D, 33C, 35C, 35D, 37C, 37D, 37E, 39E, 40B and 40C.
Yeast-like and fine cotton candy like, mold-like, non-septated hyphae organisms detected in unit # 36B.
No viable microorganisms detected in thirty (30) of seventy eight (78) units tested (units # 1, 2, 5, 9, 11, 28C ,29B, 29E, 30B, 31A, 31E, 32E, 33D, 33E, 34A, 34B, 34D, 34E, 35B, 36A, 36C, 36E, 37A, 38A, 39A, 39B, 39C, 39D, 40A, 40D.
No viable microorganisms detected from swabs taken from the exterior portion of the rubber stopper of each of seventy eight (78) units cultured in Sab-Dextrose (Sab-Dex) medium.
No obvious foreign material observed under direct visual examination of the seventy eight (78) of seventy eight (78) units individually examined.
All media, equipment, environmental and system controls were negative for growth.

Lab Conclusion Date	Lab Conclusion Made By
12/10/2012	Braut Taormina,Jasna

12/12/12

RECEIVED DEC 14 2012 NEW ORLEANS COMPLIANCE BRANCH HFR-SE440

FDA_E00277930

Flag:

ANALYST WORKSHEET	1. PRODUCT Methylpred. AC(PF) 80MG/ML Injectable		2. SAMPLE NO. 764940
3. SEALS X INTACT ___ NONE ___ BROKEN	4. DATE RECEIVED 10/5/2012	5. RECEIVED FROM Elvis Leslie	6. DISTRICT OR LABORATORY NRL

7. DESCRIPTION OF SAMPLE One brown paper bag officially sealed as "764940, 10/2/2012, Marshall H. Kinsey, Investigator" containing a total of twenty seven (27) intact individuals units (vials), and forty (42) intact foil packs containing 5 vials each of product; for a total of 69 subs which is a total of 237 units. Each vial and foil packs of product were placed in a whirl-pak bag individually. Whirl-pak bags were identified as "764940, 10/02/12 MHR Subs" 1 to 69.Form FDA 525 attached. Sample received at ambient temperature.

8. NET CONTENTS	_NOT APPLICABLE DECLARE/UNITS 1 ml _X_NOT DETERMINED AMOUNT FOUND ___ ___UNITS EXAMINED % OF DECLARED ___	9. LABELING	1 set & 2 sets copies of ___ORIGINAL SUBMITTED _____ PHOTOCOPIES SUBMITTED _____ NONE

10. SUMMARY OF ANALYSIS

A. CONTAINER: Primary container: Clear glass vial with a gray rubber stopper under a crimp metal closure and a white pop off plastic dust cover measuring approximately 3.5 cm in height and 1.0 cm in base diameter.
Secondary container: Foil bag with ziplock type closure measuring approximately 12cm H x 11.5cm W.

B. LABELING: Commercially manufactured pressure sensitive paper label affixed around glass vial.

C. CODE: "Lot#08102012@51 Discard after 2/6/2013" printed on paper label affixed around glass vial.

D. PRODUCT: White opaque free flowing suspension.

E. ANALYSIS: Examination for viable microorganism. Sterility analysis. Direct visual examination.
Exterior rubber stopper for objectionable microorganism.

F. METHOD: USP 35-NF 30, 2012 Section <71> Sterility Test.Vol.1 pp 69-74
Sterility Analytical Manual, 3rd Edition, August 1997, pp. 5-17
See p. 4 for methodology.

G. UNITS TESTED: Seventy eight (78) units tested.

H. RESULTS: Viable microorganisms detected in forty eight (48) of seventy eight (78) units tested.
Yeast-like organisms detected in units # 3, 4, 6, 7, 8, 10, 13, 28E, 29A, 29D, 30A, 30D, 30E, 31B, 31D,32B, 33A, 33B, 34C, 35A, 35E, 36D, 37B, 38B, 38C, 38D, 38E,40E.
Yeast-like and mold-like organisms detected in units #12, 28A, 28B, 28D, 29C, 30C,31C, 32A, 32C, 32D, 33C, 35C 35D, 37C, 37D, 37E, 39E, 40B, 40C.
Yeast-like and fine cotton candy like, mold-like, non-septated hyphae organisms detected in unit 36B.
No viable microorganisms detected in thirty (30) of seventy eight (78) units tested (Units # 1,2, 5, 9, 11, 28C, 29B, 29E, 30B, 31A, 31E, 32E, 33D, 33E, 34A, 34B, 34D, 34E, 35B, 36A, 36C, 36E, 37A, 38A, 39A, 39B, 39C, 39D, 40A, 40D.
No viable microorganisms detected from swabs taken from the exterior portion of the rubber stopper of each of seventy eight (78) units cultured in Sab-Dextrose (Sab-Dex) medium.
No obvious foreign material observed under direct visual examination of the seventyeight (78) of seventyeight (78) units individually examined.
All media, equipment, environmental and system controls were negative for growth.

11. RESERVE SAMPLE: See page # 2

12. ANALYST SIGNATURE	13. WORK SHEET CHECK	
Haydee B. Romero (x) Broke Seal 10/5/12 Haydee B Romero		a. BY [signature] Ph.D b. DATE 12/10/12
Jerena Brout-Thorhine, JASNA BRAUT-THORHINA	14. DATE REPORTED	
[signature] (Daniel J. O'Reilly)		12/10/12

NRL-MSB 160Version1.0
Electronic Version of 431

Attachments: A - F

FDA_E00277931

GENERAL CONTINUATION SHEET	PRODUCT: Methylpred. AC(PF) 80MG/ML Injectable	SAMPLE NO. 764940

11. RESERVE SAMPLE: Brown paper bag officially sealed "764940, 10/5/2012, Haydee B. Romero" containing a total of fourteen (14) intact (individuals vials) subs, twenty nine (29) intact (foil packs) subs for a total of 145 units, which represent a total of 43 intact subs which is a total of 159 intact units. There is also a total of thirteen (13) empty (individuals vials) subs , thirteen (13) open (foil packs) subs for a total of 65 empty units; which represent a total of 26 open empty subs which is a total of 78 units of which the entire content has been used in analysis. Each unit is identified as "764940 10/5/12 HR". Two (2) whirl pak bags officially sealed "764940, 10/10/12, Haydee B. Romero, Analyst". Each bag contains eight isolates on Sab-Dextrose agar slant; slants identified as "Sample # 764940 Sub#12-1 (pink colony) 10/10/12 HR", "Sample # 764940 Sub #12-2 (gray colony) 10/10/12 HR", "Sample # 764940 Sub # 29A (pink colony) 10/10/12 HR", "Sample # 764940 Sub # 36B 10/10/12 HR", "Sample # 764940 Sub#37D-1 (pink colony) 10/10/12 HR", Sub #37D-2 (gray colony) 10/10/12 HR", "Sample # 764940 Sub#39E-1 (pink colony) 10/10/12 HR", "Sub #39E-2 (gray colony) 10/10/12 HR". One bag was shipped to CDC on 10/11/12, for further identification and the other bag held within a secured refrigerator at NRL. One label and one empty pack were sacrificed to include with analytical worksheet. Sample kept under lock and key until returned to sample custodian.

ANALYST(S) Haydee B Romero

GENERAL CONTINUATION SHEET	PRODUCT Methylpred. AC(PF) 80mg/mL Injectable	SAMPLE NO. 764940

STERILITY MEDIA & EQUIPMENT CONTROL SHEET

Incubation Started: 10/5/12 By: HR

CONTROLS:

Environmental Monitoring: Two Blood agar plates exposed for the duration of the analysis. (Maximum time of exposure is 1 hour)

Agar Plate Growth: 0 bacterial colonies

0 mold colonies

0 yeast colonies

Media and Equipment Quality Assurance Numbers and Control Results:

ITEM	QA #	Results	ITEM	QA #	Results
Thioglycollate Broth	276-12	Neg	Millipore Forceps	N/A	N/A
Soybean Casein Digest Medium	177-12	Neg	Manifolds	N/A	N/A
Rinse Fluid A	N/A	N/A	Syringes R'd8/25/98 BD ICC 25G 5/8	Lot 0K345	Neg
Rinse Fluid D	N/A	N/A	Beakers	131-12	N/A
Malt Extract Agar(MEA)	276-12	Neg	Chlortetracycline	242-12	N/A
3% Hydrogen Peroxide R'd 3/27/12	Lot11524	N/A	Swabs R'd 9/14/11	Lot2828	Neg
70%Filter Sterilized alcohol	264-11	N/A	Membranes .22microns	N/A	N/A
			Membranes .45microns	N/A	N/A
Wipes	176-12	N/A	10" Forceps	047-12	Neg
10 ml Sabdex Broth	276-12	Neg	Phosphate Buffer	276-12	Neg
System Control	011-11	Neg	Other/Blood Agar BBL	Lot 2220296	Neg

22.5+/-2.5C Incubator 1776

32.5+/-2.5 Incubator 1958

Neg =Negative

N/A=Not Applicable

ANALYST(S): Haydee B Romero

Page 3 of 31 Pages

General continuation sheet	Product Methylpred. AC (PF) 80MG/ML Injectable	Sample No. 764940

Methodology-Direct inoculation
Sample preparation , swabbing under dust cap and sterility testing (Vials)

1. Sample Preparation:
The number of unit (s) (Seventyeight (78) to be examined was/were removed from the sample container under the laminar flow hood and all units were placed in sterile bag. The bag was disinfected using *3% H2O2* disinfectant solution. The disinfected bag then placed inside the disinfected stainless steel pass thru of the clean room and left for an hour. Analyst wore sterile latex rubber gloves, sterile sleeve, hair net and a mask during this procedure ( ).

2. Preparation of the analytical area and personnel:
Within the gowning area the analyst (s) dressed in a garment (s) consisting of hair net, mask, shoe cover, sterile hood, sterile jumpsuit, sterile booties and sterile latex rubber gloves. All transfers of product to growth medium were aseptically performed within a horizontal laminar flow hood (LFH) and the Bio safety cabinet (BSC) located within the bio-clean room. All surfaces within the LFH and BSC were thoroughly disinfected with *Filter sterilized 70% alcohol* prior to analysis of the sample ( ).

3. Analytical procedures:
All units were placed within the LFH. For each unit the flip off dust cap was aseptically removed and by using sterile cotton swap moisten in sterile *PB Buffer*, the exposed rubber stopper area was wiped and the swab was aseptically transferred to a tube containing 10 ml of sterile *Sab-Dextrose* (Sab-Dex) medium ( ). All tested unit (s) was/were then transferred to another LFH hood within the clean room for disinfection ( ). Each unit was wiped with *3% H2O2* disinfectant solution and left to dry for up to one (1) hour ( ). All disinfected unit(s) was/were transferred to the BSC within the clean room ( ). Within the BSC within the Bio clean room. These units were again disinfected with *Filter sterilized 70% alcohol* and left to air dry under the BSC ( ). For each unit using sterile 1 CC syringe 0.5 ml of the contents were aseptically delivered into SCD medium and 0.5 ml delivered into Fl. Thio. medium ( ).
The remaining droplets in the syringe were then aseptically transferred unto a MEA agar plate ( )

4. Controls:
Media: All tubes of Fl. Thio medium, SCD medium , 10 ml Sab-dex medium ,blood agar plates, and *MEA* agar plates were pre-incubated prior to use. One un-inoculated tube of each medium was incubated with the test tubes as closed controls ( ).
Swab: One sterile swab was aseptically transferred to a tube containing 10 ml of sterile Sab-dex medium
Equipment: Two (2) 10" forceps were each dipped into one tube each of SCD and Fl. Thio. media ( ).
Syringe: Two (2) syringes were used to withdraw media from each of SCD and Fl. Thio. Media and expelled it back to their respective tubes.
System control: To monitor the sterility of the analytical technique, a system control was used. *One sterile vial of 0.1% peptone water was aseptically opened to expose the rubber stopper by using a sterile 10" forceps, this unit was tested using the same analytical procedure employed in setting up the sample* ( ).

5. Environmental: Two *blood* agar plates were exposed for the duration of the analysis on the right and left sides of the hood working area for each step of the analysis( ). One tube each of Fl. Thio. medium, SCD medium and SabDex medium were opened and exposed for the duration of the analysis as opened controls ( ).

6. Incubation:
Tubes of SCD medium were incubated 14 days at 22.5 +/- 2.5 °C. Tubes of Fl. Thio. medium were incubated 14 days at 32.5+/ - 2.5 °C. Tubes of Sab-Dextrose medium were incubated 14 days at 30 °C. All tubes were observed periodically for indication of possible growth (i .e. turbidity) ( ). The MEA agar plates were incubated at 22.5 +/ - 2.5 °C and were observed for growth for up to 14 days ( )

7. Subculture of presumptive positive tubes: See p. 22-26

( )= Analyst performing procedure

ANALYST(S) Haydee B Romero

GENERAL CONTINUATION SHEET	PRODUCT Methylpred. AC(PF) 80MG/ML Injectable	SAMPLE NO. 764940

DAILY OBSERVATIONS

SAMPLE TEST

Date Incubation Started 10/5/12 HRC

SUB / Composite	Thio/SCD DAYS INCUBATED 1	2	3	4	5	6	7	8	9	10	11	12	13	14	Final Results
1				(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)			(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)	See page #1 and pages 22-31
2				(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)			(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)	
3				(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)			(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)	
4				(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)			(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)	
5				(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)			(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)	
6				(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)			(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)	
7				(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)			(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)	
8				(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)			(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)	
9				(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)			(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)	
10				(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)			(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)	
11				(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)			(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)	
12				(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)			+/(+)	+/(+)	+/(+)	+/(+)	+/(+)	
13				(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)			(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)	
N/A															
DATE / INITIAL	10/4 W	10/7 W	10/8 H	10/9 HRC	10/10 HRC	10/11 HRC	10/12 HRC	10/13 W	10/14 W	10/15 HRC	10/16 HRC	10/17 HRC	10/18 HRC	10/19 HRC	

Upon recovering the sample a direct visual examination was done. No obvious foreign material observed under direct visual examination of the 78 units individually examined.

+ = obvious growth observed

(+) = Presumptive positive, unable to identify growth due to the turbidity nature of the product, all Thio/SCD tubes were streaked to MacConkey agar, Soybean Casein Digest Agar and Malt extract agar after 14 days.

W = weekend H = Holidays

ANALYST(S) Haydee B. Romero

GENERAL CONTINUATION SHEET	PRODUCT Methylpred. AC (PF) 80 MG/ML Injectable	SAMPLE NO. 764940

DAILY OBSERVATIONS

SAMPLE TEST

Date Incubation Started 10/5/12

SUB / Composite	Thio/SCD DAYS INCUBATED 1	2	3	4	5	6	7	8	9	10	11	12	13	14	Final Results
28 A				(+)	(+)	(+)	(+)			+	+	+	+	+	See page # 1
28 B				(+)	(+)	(+)	(+)			(+)	(+)	(+)	(+)	(+)	and pages 22-31
28 C				(+)	(+)	(+)	(+)			(+)	(+)	(+)	(+)	(+)	
28 D				(+)	(+)	(+)	(+)			+	+	+	+	+	
28 E				(+)	(+)	(+)	(+)			(+)	(+)	(+)	(+)	(+)	
29 A				(+)	(+)	(+)	(+)			(+)	(+)	(+)	(+)	(+)	
29 B				(+)	(+)	(+)	(+)			(+)	(+)	(+)	(+)	(+)	
29 C				(+)	(+)	(+)	(+)			+	+	+	+	+	
29 D				(+)	(+)	(+)	(+)			(+)	(+)	(+)	(+)	(+)	
29 E				(+)	(+)	(+)	(+)			(+)	(+)	(+)	(+)	(+)	
30 A				(+)	(+)	(+)	(+)			(+)	(+)	(+)	(+)	(+)	
30 B				(+)	(+)	(+)	(+)			(+)	(+)	(+)	(+)	(+)	
30 C				(+)	(+)	(+)	(+)			+	+	+	+	+	
30 D				(+)	(+)	(+)	(+)			(+)	(+)	(+)	(+)	(+)	
30 E				(+)	(+)	(+)	(+)			(+)	(+)	(+)	(+)	(+)	
DATE / INITIAL	10/6 W	10/7 W	10/8 H	10/9 M	10/10 M	10/11 M	10/12 M	10/13 W	10/14 W	10/15 M	10/16 M	10/17 M	10/18 M	10/19 M	

See page 5 for Direct Visual Examination

+ = obvious growth observed

(+) = presumptive positive, unable to identify growth due to turbidity nature of the product, all Thio/SCD Tubes were streaked to MacConkey agar, Soybean Casein Digest Agar and Malt extract agar after 14 days.

W = Weekend H = Holidays

ANALYST(S) Hayden B Renner

GENERAL CONTINUATION SHEET	PRODUCT Methylpred. AC(PF) 80MG/ML Injectable	SAMPLE NO. 764940

DAILY OBSERVATIONS

SAMPLE TEST

Date Incubation Started 10/5/12 [illegible]

SUB / Composite	Thio/SCD DAYS INCUBATED 1	2	3	4	5	6	7	8	9	10	11	12	13	14	Final Results
31 A				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	See page #1 and pages 22-31
31 B				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	
31 C				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	
31 D				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	
31 E				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	
32 A				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	
32 B				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	
32 C				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	
32 D				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	
32 E				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	
33 A				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	
33 B				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	
33 C				(+) (+)	(+) (+)	(+) (+)	(+) (+)			+ (+)	+ (+)	+ (+)	+ (+)	+ (+)	
33 D				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	
33 E				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	↓
DATE / INITIAL	10/6 W	10/7 W	10/8 H	10/9 [illegible]	10/10 [illegible]	10/11 [illegible]	10/12 [illegible]	10/13 W	10/14 W	10/15 [illegible]	10/16 [illegible]	10/17 [illegible]	10/18 [illegible]	10/19 [illegible]	

See page 5 for Direct Visual Examination

+ = obvious growth observed

(+) = presumptive positive, unable to identify growth due to the turbidity nature of the product, all thio/SCD tubes were streaked to MACconkey agar, Soybean Casein Digest Agar and Malt Extract agar after 14 days.

W = Weekend H = Holidays

ANALYST(S) Hayden B Romero

GENERAL CONTINUATION SHEET	PRODUCT Methylpred. AC(PF)80MG/ML Injectable	SAMPLE NO. 764940

DAILY OBSERVATIONS

SAMPLE TEST

Date Incubation Started 10/5/12 MR

SUB / Composite	Thio/SCD DAYS INCUBATED 1	2	3	4	5	6	7	8	9	10	11	12	13	14	Final Results
34 A				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	See page 11 and pages 22-31
34 B				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	
34 C				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	
34 D				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	
34 E				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	
35 A				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	
35 B				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	
35 C				(+) (+)	(+) (+)	(+) (+)	(+) (+)			+ +	+ +	+ +	+ +	+ +	
35 D				(+) (+)	(+) (+)	(+) (+)	(+) (+)			+ +	+ +	+ +	+ +	+ +	
35 E				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	
36 A				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	
36 B				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	
36 C				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	
36 D				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	
36 E				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	
DATE / INITIAL	10/6 W	10/7 W	10/8 H	10/9 MR	10/10 MR	10/11 MR	10/12 MR	10/13 W	10/14 W	10/15 MR	10/16 MR	10/17 MR	10/18 MR	10/19 MR	

See page 5 for Direct Visual Examination

+ = obvious growth observed

(+) = presumptive positive, unable to identify growth due to the turbidity inherent to the product, all Thio/SCD tubes were streaked to Mocconkey agar, Soybean Casein Digest agar and Half & Half agar after 14 days

W = Weekend H = Holidays

ANALYST(S)

Haydee G Romero

GENERAL CONTINUATION SHEET	PRODUCT Methylpred. AC (PF) 80MG/ML Injectable	SAMPLE NO. 764980

DAILY OBSERVATIONS

SAMPLE TEST

Date Incubation Started 10/5/12 th

SUB / Composite	Thio/SCD DAYS INCUBATED 1	2	3	4	5	6	7	8	9	10	11	12	13	14	Final Results
37 A				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	See page #1 and pages 22-31
37 B				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	
37 C				(+) (+)	(+) (+)	(+) (+)	(+) (+)			+ (+)	+ (+)	+ (+)	+ (+)	+ (+)	
37 D				(+) (+)	(+) (+)	(+) (+)	(+) (+)			+ +	+ +	+ +	+ +	+ +	
37 E				(+) (+)	(+) (+)	(+) (+)	(+) (+)			+ (+)	+ (+)	+ (+)	+ (+)	+ (+)	
38 A				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	
38 B				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	
38 C				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	
38 D				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	
38 E				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	
39 A				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	
39 B				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	
39 C				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	
39 D				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	
39 E				(+) (+)	(+) (+)	(+) (+)	(+) (+)			+ (+)	+ (+)	+ (+)	+ (+)	+ (+)	
DATE / INITIAL	10/6 W	10/7 W	10/8 H	10/9 M	10/10 M	10/11 M	10/12 M	10/13 W	10/14 W	10/15 M	10/16 M	10/17 M	10/18 M	10/19 M	

See page 5 for Direct Visual Examination

+ = obvious growth observed.

(+) = Presumptive positive, unable to identify growth due to the turbidity nature of the product, all the SCD tubes were streaked to Mocconkey agar, Soybean Casein Digest agar and Halt Enrichment broth after 14 days

W = Weekend H = Holidays

ANALYST(S) Haydee B Romero

Page 9 of 31 Pages

GENERAL CONTINUATION SHEET	PRODUCT Methylpred. AC (PF) 80MG/ML Injectable	SAMPLE NO. 764940

DAILY OBSERVATIONS

SAMPLE TEST

Date Incubation Started 10/5/12 10:00

SUB / Composite	Thio/SCD DAYS INCUBATED 1	2	3	4	5	6	7	8	9	10	11	12	13	14	Final Results
40 A				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	See page #1
40 B				(+) (+)	(+) (+)	(+) (+)	(+) (+)			+ (+)	+ (+)	+ (+)	+ (+)	+ (+)	and pages 22-31
40 C				(+) (+)	(+) (+)	(+) (+)	(+) (+)			+ (+)	+ (+)	+ (+)	+ (+)	+ (+)	
40 D				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	
40 E				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	(+) (+)	
System Control				– –	– –	– –	– –			– –	– –	– –	– –	– –	No Growth
Open Media				– –	– –	– –	– –			– –	– –	– –	– –	– –	
Closed Media				– –	– –	– –	– –			– –	– –	– –	– –	– –	
Syringes				– –	– –	– –	– –			– –	– –	– –	– –	– –	
10" forceps				– –	– –	– –	– –			– –	– –	– –	– –	– –	
N/A															
DATE / INITIAL	10/6 W	10/7 W	10/8 H	10/9 [illegible]	10/10 [illegible]	10/11 [illegible]	10/12 [illegible]	10/13 W	10/14 W	10/15 [illegible]	10/16 [illegible]	10/17 [illegible]	10/18 [illegible]	10/19 [illegible]	

See page 5 for Direct Visual Examination

+ = obvious growth observed

(+) = presumptive positive, unable to identify growth due to the turbidity nature of the product, all Thio/SCD tubes were streaked to Mac Conkey agar, Soybean Casein Digest agar and Malt extract agar after 14 days

W = Weekend H = Holiday

ANALYST(S) Haydee B. Ramos

GENERAL CONTINUATION SHEET	PRODUCT Methylprd.AC(PF) 80 MG/ML Injectable	SAMPLE NO. 764990

DAILY OBSERVATIONS

From swabs taken from the exterior portion of the rubber stopper of each sub.

SAMPLE TEST

Date Incubation Started 10/5/12 HR

SUB / Composite	swab in Sab Dex broth DAYS INCUBATED 1	2	3	4	5	6	7	8	9	10	11	12	13	14	Final Results
1				–	–	–	–			–	–	–	–	–	No Growth
2				–	–	–	–			–	–	–	–	–	
3				–	–	–	–			–	–	–	–	–	
4				–	–	–	–			–	–	–	–	–	
5				–	–	–	–			–	–	–	–	–	
6				–	–	–	–			–	–	–	–	–	
7				–	–	–	–			–	–	–	–	–	
8				–	–	–	–			–	–	–	–	–	
9				–	–	–	–			–	–	–	–	–	
10				–	–	–	–			–	–	–	–	–	
11				–	–	–	–			–	–	–	–	–	
12				–	–	–	–			–	–	–	–	–	
13				–	–	–	–			–	–	–	–	–	
N/A															
↓															
DATE / INITIAL	10/6 W	10/7 W	10/8 H	10/9 HR	10/10 HR	10/11 HR	10/12 HR	10/13 W	10/14 W	10/15 HR	10/16 HR	10/17 HR	10/18 HR	10/19 HR	

W= weekend L= Leave H= Holidays O= other (Explain) – = No Growth

ANALYST(S) Hayden & Romero

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GENERAL CONTINUATION SHEET	PRODUCT Methylpred AC (PF) 80MG/ML Injectable	SAMPLE NO. 764940

DAILY OBSERVATIONS

From swabs Taken from the exterior portion of the rubber stoppers of each sub.

SAMPLE TEST

Date Incubation Started 10/5/12 KR

SUB / Composite	swab in Sab Dex broth						DAYS INCUBATED								Final Results
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	
28 A				—	—	—	—			—	—	—	—	—	No Growth
28 B				—	—	—	—			—	—	—	—	—	
28 C				—	—	—	—			—	—	—	—	—	
28 D				—	—	—	—			—	—	—	—	—	
28 E				—	—	—	—			—	—	—	—	—	
29 A				—	—	—	—			—	—	—	—	—	
29 B				—	—	—	—			—	—	—	—	—	
29 C				—	—	—	—			—	—	—	—	—	
29 D				—	—	—	—			—	—	—	—	—	
29 E				—	—	—	—			—	—	—	—	—	
30 A				—	—	—	—			—	—	—	—	—	
30 B				—	—	—	—			—	—	—	—	—	
30 C				—	—	—	—			—	—	—	—	—	
30 D				—	—	—	—			—	—	—	—	—	
30 E				—	—	—	—			—	—	—	—	—	
DATE / INITIAL	10/6 W	10/7 W	10/8 H	10/9 KR	10/10 KR	10/11 KR	10/12 KR	10/13 W	10/14 W	10/15 KR	10/16 KR	10/17 KR	10/18 KR	10/19 KR	

W= weekend L= Leave H= Holidays O= other (Explain) — = No Growth

ANALYST(S) Haydee B Romero

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GENERAL CONTINUATION SHEET	PRODUCT Methylpred. AC (PF) 80MG/ML Injectable	SAMPLE NO. 767940

DAILY OBSERVATIONS

From swabs Taken from The exterior portion of the rubber stopper of each sub.

SAMPLE TEST

Date Incubation Started 10/5/12 KM

SUB / Composite	swab in Sab Dex broth						DAYS INCUBATED								Final Results
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	
31 A				–	–	–	–			–	–	–	–	–	No Growth
31 B				–	–	–	–			–	–	–	–	–	
31 C				–	–	–	–			–	–	–	–	–	
31 D				–	–	–	–			–	–	–	–	–	
31 E				–	–	–	–			–	–	–	–	–	
32 A				–	–	–	–			–	–	–	–	–	
32 B				–	–	–	–			–	–	–	–	–	
32 C				–	–	–	–			–	–	–	–	–	
32 D				–	–	–	–			–	–	–	–	–	
32 E				–	–	–	–			–	–	–	–	–	
33 A				–	–	–	–			–	–	–	–	–	
33 B				–	–	–	–			–	–	–	–	–	
33 C				–	–	–	–			–	–	–	–	–	
33 D				–	–	–	–			–	–	–	–	–	
33 E				–	–	–	–			–	–	–	–	–	
DATE / INITIAL	10/6 W	10/7 W	10/8 H	10/9 KM	10/10 KM	10/11 KM	10/12 KM	10/13 W	10/14 W	10/15 KM	10/16 KM	10/17 KM	10/18 H	10/19 KM	

W= weekend L= Leave H= Holidays O= other (Explain) – = No Growth

ANALYST(S) Hayden B Romero

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GENERAL CONTINUATION SHEET	PRODUCT Methylpred. AC (PF) 80MG/ML Injectable	SAMPLE NO. 769440

DAILY OBSERVATIONS

From swabs taken from the exterior portion of the rubber stopper of each sub

SAMPLE/TEST

Date Incubation Started 10/5/12 HR

SUB / Composite	swab in Sab Dex broth						DAYS INCUBATED								Final Results
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	
34 A				–	–	–	–			–	–	–	–	–	No Growth
34 B				–	–	–	–			–	–	–	–	–	
34 C				–	–	–	–			–	–	–	–	–	
34 D				–	–	–	–			–	–	–	–	–	
34 E				–	–	–	–			–	–	–	–	–	
35 A				–	–	–	–			–	–	–	–	–	
35 B				–	–	–	–			–	–	–	–	–	
35 C				–	–	–	–			–	–	–	–	–	
35 D				–	–	–	–			–	–	–	–	–	
35 E				–	–	–	–			–	–	–	–	–	
36 A				–	–	–	–			–	–	–	–	–	
36 B				–	–	–	–			–	–	–	–	–	
36 C				–	–	–	–			–	–	–	–	–	
36 D				–	–	–	–			–	–	–	–	–	
36 E				–	–	–	–			–	–	–	–	–	
DATE / INITIAL	10/6 W	10/7 W	10/8 H	10/9 HR	10/10 HR	10/11 HR	10/12 HR	10/13 W	10/14 W	10/15 HR	10/16 HR	10/17 HR	10/18 HR	10/19 HR	

W= weekend L= Leave H= Holidays O= other (Explain) – = No Growth

ANALYST(S) Hayden B Romero

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GENERAL CONTINUATION SHEET	PRODUCT Methylpred. AC (PF) 80 MG/ML Injectable	SAMPLE NO. 764940

DAILY OBSERVATIONS

From swabs Taken from the exterior portion of the rubber stopper of each sub

SAMPLE TEST

Date Incubation Started 10/5/12 HM

SUB / Composite	swab in Sab Dex broth DAYS INCUBATED 1	2	3	4	5	6	7	8	9	10	11	12	13	14	Final Results
37 A				–	–	–	–			–	–	–	–	–	No Growth
37 B				–	–	–	–			–	–	–	–	–	
37 C				–	–	–	–			–	–	–	–	–	
37 D				–	–	–	–			–	–	–	–	–	
37 E				–	–	–	–			–	–	–	–	–	
38 A				–	–	–	–			–	–	–	–	–	
38 B				–	–	–	–			–	–	–	–	–	
38 C				–	–	–	–			–	–	–	–	–	
38 D				–	–	–	–			–	–	–	–	–	
38 E				–	–	–	–			–	–	–	–	–	
39 A				–	–	–	–			–	–	–	–	–	
39 B				–	–	–	–			–	–	–	–	–	
39 C				–	–	–	–			–	–	–	–	–	
39 D				–	–	–	–			–	–	–	–	–	
39 E				–	–	–	–			–	–	–	–	–	
DATE / INITIAL	10/6 W	10/7 W	10/8 H	10/9 HM	10/10 HM	10/11 HM	10/12 HM	10/13 W	10/14 W	10/15 HM	10/16 HM	10/17 HM	10/18 HM	10/19 HM	

W= weekend L= Leave H= Holidays O= other (Explain) – = No Growth

ANALYST(S) Hayde B. Romero

GENERAL CONTINUATION SHEET	PRODUCT Methylpred. AC (PF) 80MG/ML Injectable	SAMPLE NO. 764940

DAILY OBSERVATIONS

From swabs taken from the exterior portion of the rubber stopper of each sub.

SAMPLE TEST

Date Incubation Started 10/5/12 BR

SUB Composite	swab in Sab Dex broth DAYS INCUBATED 1	2	3	4	5	6	7	8	9	10	11	12	13	14	Final Results
40 A				–	–	–	–			–	–	–	–	–	No Growth
40 B				–	–	–	–			–	–	–	–	–	
40 C				–	–	–	–			–	–	–	–	–	
40 D				–	–	–	–			–	–	–	–	–	
40 E				–	–	–	–			–	–	–	–	–	
Swab Control				–	–	–	–			–	–	–	–	–	
Open control				–	–	–	–			–	–	–	–	–	
Closed Control				–	–	–	–			–	–	–	–	–	
System Control				–	–	–	–			–	–	–	–	–	
N/A															
DATE / INITIAL	10/6 W	10/7 W	10/8 H	10/9 BR	10/10 BR	10/11 BR	10/12 BR	10/13 W	10/14 W	10/15 BR	10/16 BR	10/17 BR	10/18 BR	10/19 BR	

W= weekend L= Leave H= Holidays O= other (Explain) – = No Growth

ANALYST(S) Hayden B Lowen

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GENERAL CONTINUATION SHEET	PRODUCT Methylpred. AC (PF) 80 MG/ML Injectable	SAMPLE NO. 764940

Direct inoculation of product on agar media N/A=Not Applicable

SUB # 10/8/12	Agar type used	Plates read 10/9/12 10/9/12	Gram stain 10/9/12	Subculture on 10/10/12	Biochemical identification N/A	Results
1	MEA	–	N/A			
2	↓	–	N/A			
3		+	Y			Yeast like organisms.
4		+	* *			
5		–	N/A			
6		+	* *			
7		+	↓			
8		+				
9		–	N/A			
10		+	* *			
11		–	N/A			
12		+	Y & M	* Sab-dex Skrt		Yeast-like and Mold like organisms.
13		+	* *			
28 A		+	↓			
28 B		+				
28 C		–	N/A			
28 D		+	* *			
28 E	↓	+	↓			
N/A						
↓						

ANALYST(S) Haydee B Romero

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Key: Y = Yeast-like cells M = Septated Hyphae

GENERAL CONTINUATION SHEET	PRODUCT Methylpred. AC (PF) 80MG/ML Injectable	SAMPLE NO. 764940

Direct inoculation of product on agar media N/A=Not Applicable

SUB # 10/5/12 HDL	Agar type used	Plates read 10/9/12 HDL 10/9/12 HDL	Gram stain 10/9/12 HDL	Subculture on 10/10/12 HDL	Biochemical identification N/A	Results
29 A	MEA	+	Y	Sab-dex Slant		Yeast-like organisms
29 B		−	N/A			
29 C		+	* *			
29 D		+				
29 E		−	N/A			
30 A		+	* *			
30 B		−	N/A			
30 C		+	* *			
30 D		+				
30 E		+				
31 A		−	N/A			
31 B		+	* *			
31 C		+				
31 D		+				
31 E		−	N/A			
32 A		+	* *			
32 B		+				
32 C		+				
32 D		+				
32 E		−	N/A			

ANALYST(S) Haydee B Romero

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Key: Y = Yeast-like cells M = Septated Hyphae

GENERAL CONTINUATION SHEET	PRODUCT Methylpred. AC(PF) 80MG/ML	SAMPLE NO. 764940

Direct inoculation of product on agar media N/A=Not Applicable

SUB # 10/5/12 [illegible]	Agar type used	Plates read 10/9/12 [illegible] 10/9/12 [illegible]	Gram stain 10/9/12 [illegible]	Subculture on 10/10/12 [illegible]	Biochemical identification N/A	Results
33 A	MEA	+	* *			
33 B	↓	+	↓			
33 C	↓	+	↓			
33 D	↓	–	N/A			
33 E	↓	–	N/A			
34 A	↓	–	N/A			
34 B	↓	–	N/A			
34 C	↓	+	* *			
34 D	↓	–	N/A			
34 E	↓	–	N/A			
35 A	↓	+	* *			
35 B	↓	–	N/A			
35 C	↓	+	* *			
35 D	↓	+	↓			
35 E	↓	+	↓			
36 A	↓	–	N/A			
36 B	↓	+	MC	Sab-dex Slant		Mold-like organism
36 C	↓	–	N/A			
36 D	↓	+	* *			
36 E	↓	–	N/A			

ANALYST(S) Hayden B Romero

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Key: Y = Yeast-like Cells M = Septated Hyphae MC = non-septated Hyphae

GENERAL CONTINUATION SHEET	PRODUCT Methylpred. AC (PF) 80 MG/ML Injectable	SAMPLE NO. 764940

Direct inoculation of product on agar media N/A=Not Applicable

SUB # 10/5/12	Agar type used	Plates read 10/19/12 10/8/12	Gram stain 10/9/12	Subculture on 10/10/12	Biochemical identification N/A	Results
37 A	MEA	–	N/A			
37 B		+	* *			
37 C		+				
37 D		+	Y & M	Sab-dex Slant		Yeast-like and mold like organisms.
37 E		+	* *			
38 A		–	N/A			
38 B		+	* *			
38 C		+				
38 D		+				
38 E		+				
39 A		–	N/A			
39 B		–	N/A			
39 C		–	N/A			
39 D		–	N/A			
39 E		+	Y & M	Sab-dex Slant		Yeast-like and mold like organisms
40 A		–	N/A			
40 B		+	* *			
40 C		+				
40 D		–	N/A			
40 E		+	* *			

ANALYST(S) Hayglee B Romero

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Key: Y = Yeast-like cells M = Septated Hyphae

GENERAL CONTINUATION SHEET	PRODUCT Methylpred. AC (PF) 80 MG/ML Injectable	SAMPLE NO. 764940

Direct inoculation of product on agar media N/A=Not Applicable

SUB #	Agar type used	Plates read 10/19/12 10/9/12	Gram stain N/A	Subculture on N/A	Biochemical identification N/A	Results
Blank Control	MEA	—				NO GROWTH
N/A						
*	A representative portion of positive subs were					
	subcultured to Sab-dex slants in duplicate sets					
	(Sub 12 = yeast like colony + mold like colony, sub 29A =					
	yeast like colony, Sub 36 B = mold-like colony,					
	Sub 37 D = yeast like colony + mold-like colony,					
	Sub 39 E = yeast like colony + mold-like colony)					
	One set for shipment to CDC for further identification					
	and the other set for storage at NRL					
**	Colony morphology same as sub # 3 and sub 29A					
Sab Dex agar slants QA # 279-12						
Microscope 282						

ANALYST(S) Hayden G Romero

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GENERAL CONTINUATION SHEET	PRODUCT Methylpred. AC (PF) 80MG/ML	SAMPLE NO. 769940

Results from Subculture of THIO Medium on agar plates

N/A=Not Applicable

SUB #	Agar used 10/22/12 HR	8/11/2/12 HR		Microscopic examination from N/A			Colony Morphology	Subculture on	Biochemical identification N/A
10/19/12 HR	HAC	HEA	MSCD				10/22/12 HR	N/A	
1	NG	NG	NG				N/A		
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12		+	+				MEA MSCD > M		
13		NG	NG				N/A		
28 A		+	+				MEA MSCD > M		
28 B		NG	NG				N/A		
28 C		NG	NG				N/A		
28 D		+	+				MEA MSCD > M		
28 E		NG	NG				N/A		
N/A									
↓									

ANALYST(S) Hayden B Remen

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Key: Y = Pink colony M = Black/Gray metal-like colony NG = no growth

GENERAL CONTINUATION SHEET	PRODUCT Methylpred. AC(PF) 80MG/ML	SAMPLE NO. 764940

Results from Subculture of THIO Medium on agar plates

N/A=Not Applicable

SUB #	Agar used 10/22/12 HL & 11/2/12 HL			Microscopic examination from N/A			Colony Morphology	Subculture on	Biochemical identification N/A
10/19/12 HL	MAC	MEA	MSCD				10/22/12 HL	N/A	
29 A	NG	NG	NG				N/A		
29 B		NG	NG				N/A		
29 C		+	+				MEA, MSCD > M		
29 D		NG	NG				N/A		
29 E		NG	NG						
30 A		NG	NG						
30 B		NG	NG						
30 C		+	+				MEA, MSCD > M		
30 D		NG	NG				N/A		
30 E		NG	NG						
31 A		NG	NG						
31 B		NG	NG						
31 C		NG	NG						
31 D		NG	NG						
31 E		NG	NG						
32 A		NG	NG						
32 B		NG	NG						
32 C		NG	NG						
32 D		NG	NG						
32 E		NG	NG						

ANALYST(S) Hayden B Romero

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Key: Y: Pink colony M: Blackish, gray mold like colony NG = No Growth

NRL MSB NECC

Electronic Version of 431A

FDA_E00277953

GENERAL CONTINUATION SHEET	PRODUCT Methylpred.AC(PF) 80 MG/ML Injectable	SAMPLE NO. 764940

Results from Subculture of THIO Medium on agar plates

N/A=Not Applicable

SUB #	Agar used 10/22/12 HM & 11/2/12 HM			Microscopic examination from N/A			Colony Morphology	Subculture on	Biochemical identification
	MAC	MEA	MSCD				10/22/12 HM	N/A	~~N/A~~
33A	NG	NG	NG				N/A		
33B		NG	NG				N/A		
33C		+	+				MEA MSCD > M		
33D		NG	NG				N/A		
33E									
34A									
34B									
34C									
34D									
34E									
35A									
35B									
35C									
35D									
35E									
36A									
36B									
36C									
36D									
36E	✓	✓	✓				✓		

ANALYST(S) Hayden B Rowen

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Key: Y = Pink Colony M = Blackish, gray Mold-like colony NG = No growth

NRL.MSB.NECC

Electronic Version of 431A

GENERAL CONTINUATION SHEET	PRODUCT Methylpred.AC(PF) 80 MG/ML Injectable	SAMPLE NO. 764940

Results from Subculture of FH10 Medium on agar plates

N/A=Not Applicable

SUB #	Agar used 10/22/12		11/2/12	Microscopic examination from N/A			Colony Morphology	Subculture on	Biochemical identification N/A
1/19/12 HR	MAC	MEA	MSCD				10/22/12 HR	N/A	
37A	NG	NG	NG				N/A		
37B		NG	NG				N/A		
37C		+	+				MEA MSCD > M		
37D		+	+				MEA MSCD > M		
37E		+	+				MEA MSCD > M		
38A		NG	NG				N/A		
38B									
38C									
38D									
38E									
39A									
39B									
39C									
39D									
39E		+	+				MEA MSCD > M		
40A		NG	NG				N/A		
40B		+	+				MEA MSCD > M		
40C		+	+				MEA MSCD > M		
40D		NG	NG				N/A		
40E		NG	NG				N/A		

ANALYST(S) Hayden B Romero

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Key: Y = Pink Colony M = Blackish, gray Mold-like Colony NG = No Growth

NRL.MSB.NECC

Electronic Version of 431A

GENERAL CONTINUATION SHEET	PRODUCT Methylpred.AC(PF) 80 MG/ML Injectable	SAMPLE NO. 764940

Results from Subculture of THIO Medium on agar plates

N/A=Not Applicable

SUB #	Agar used 10/22/12 10/22 11/2/12			Microscopic examination from N/A			Colony Morphology	Subculture on	Biochemical identification
10/19/12	MAC	MEA	MSCD	MAC	MEA	MSCD		N/A	N/A
Blank Control	NG	NG	NG				N/A		
N/A									
QA:									
MAC: 284-12									
MEA 283-12									
MSCD 281-12									
Chlortetracycline 242-12									

ANALYST(S) Haydee B Romero

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Key: Y = Pink Colony M = Black Cloudy, gray Mold-like colony NG = No Growth

NRL.MSB.NECC

Electronic Version of 431A

GENERAL CONTINUATION SHEET	PRODUCT Methylpred. AC (PF) 80MG/ML Injectable	SAMPLE NO. 764940

Results from Subculture of SCD Medium on agar plates

N/A=Not Applicable

SUB #	Agar used 10/22/12 10/2/12			Microscopic examination from N/A			Colony Morphology	Subculture on	Biochemical identification N/A
10/19/12	MAC	MEA	MSCD				10/22/12	N/A	
1	NG	NG	NG				N/A		
2		NG	NG				N/A		
3		+	+				MEA MSCD > Y		
4		+	+				MEA MSCD > Y		
5		NG	NG				N/A		
6		+	+				MEA MSCD > Y		
7		+	+				MEA MSCD > Y		
8		+	+				MEA MSCD > Y		
9		NG	NG				N/A		
10		+	+				MEA MSCD > Y		
11		NG	NG				N/A		
12		+	+				MEA MSCD > Y		
13		+	+				MEA MSCD > Y		
28 A		+	+				MEA Y MSCD Y, M		
28 B		+	+				MEA MSCD > M		
28 C		NG	NG				N/A		
28 D		+	+				MEA Y MSCD Y, M		
28 E		+	+				MEA MSCD > Y		
N/A									

ANALYST(S) Hayden B Romero

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key: Y = Pink colony M = Blackish, gray mild-like colony NG = no Growth

GENERAL CONTINUATION SHEET	PRODUCT Methylpred. AC (PF) 80MG/ML	SAMPLE NO. 764940

Results from Subculture of SCD Medium on agar plates

N/A=Not Applicable

SUB #	Agar used 10/22/12 HR		11/2/12 HR	Microscopic examination from N/A			Colony Morphology	Subculture on	Biochemical identification N/A
10/19/12 HR	MAC	MEA	MSCD				10/22/12 HR	N/A	
29 A	NG	+	+				MEA MSCD > Y		
29 B		NG	NG				N/A		
29 C		+	+				MEA : Y MSCD : Y, M		
29 D		+	+				MEA MSCD > Y		
29 E		NG	NG				N/A		
30 A		+	+				MEA MSCD > Y		
30 B		NG	NG				N/A		
30 C		+	+				MEA : Y MSCD : Y, M		
30 D		+	+				MEA MSCD > Y		
30 E		+	+				MEA MSCD > Y		
31 A		NG	NG				N/A		
31 B		+	+				MEA MSCD > Y		
31 C		+	+				MEA : Y, M MSCD : Y		
31 D		+	+				MEA MSCD > Y		
31 E		NG	NG				N/A		
32 A		+	+				MEA : Y, M MSCD : Y		
32 B		+	+				MEA MSCD > Y		
32 C		+	+				MEA : Y MSCD : Y, M		
32 D		+	+				MEA : Y MSCD : Y, M		
32 E		NG	NG				N/A		

ANALYST(S) Haylee B Romero

PAGE 2 OF 3 PAGES

Key: Y = Pink colony M : Blackish gray mold-like colony NG = No Growth

NRL MSB NECC

Electronic Version of 431A

FDA_E00277958

GENERAL CONTINUATION SHEET	PRODUCT Methylpred. AC(PF) 80MG/ML Injectable	SAMPLE NO. 764940

Results from Subculture of SCD Medium on agar plates

N/A=Not Applicable

SUB #	Agar used 10/29/12 MAC	MEA 11/2/12 KDR	MSCD	Microscopic examination from N/A			Colony Morphology	Subculture on N/A	Biochemical identification N/A
10/19/12 KDR							10/22/12 KDR		
33 A	NG	+	+				MEA MSCD > Y		
33 B		+	+				MEA MSCD > Y		
33 C		+	+				MEA MSCD > Y		
33 D		NG	NG				N/A		
33 E		NG	NG				N/A		
34 A		NG	NG				N/A		
34 B		NG	NG				N/A		
34 C		+	+				MEA MSCD > Y		
34 D		NG	NG				N/A		
34 E		NG	NG				N/A		
35 A		+	+				MEA MSCD > Y		
35 B		NG	NG				N/A		
35 C		+	+				MEA Y MSCD: Y, M		
35 D		+	+				MEA MSCD > Y, M		
35 E		+	+				MEA MSCD > Y		
36 A		NG	NG				N/A		
36 B		+	+				MEA Y MSCD Y, MC		
36 C		NG	NG				N/A		
36 D		+	+				MEA MSCD > Y		
36 E		NG	NG				N/A		

ANALYST(S) Hayley B. Romero

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Key: Y = Pink colony M = Blackish, gray mold-like colony NG = no Growth
MC = Fine Cotton candy like, mold-like colony

NRL.MSB.NECC

Electronic Version of 431A

FDA_E00277959

GENERAL CONTINUATION SHEET	PRODUCT Methylpred. AC (PF) 80MG/ML	SAMPLE NO. 764940

Results from Subculture of SCD Medium on agar plates

N/A=Not Applicable

SUB #	Agar used 10/22/12 HDR 4/2/12 HDR			Microscopic examination from N/A			Colony Morphology	Subculture on	Biochemical identification N/A
10/19/12 HDR	MAC	MEA	MSCD				10/22/12 HDR	N/A	
37 A		NG	NG				N/A		
37 B		+	+				MEA MSCD > Y		
37 C		+	+				MEA MSCD > Y		
37 D		+	+				MEA MSCD > Y		
37 E		+	+				MEA MSCD > Y		
38 A		NG	NG				N/A		
38 B		+	+				MEA MSCD > Y		
38 C		+	+				MEA MSCD > Y		
38 D		+	+				MEA MSCD > Y		
38 E		+	+				MEA MSCD > Y		
39 A		NG	NG				N/A		
39 B		NG	NG				N/A		
39 C		NG	NG				N/A		
39 D		NG	NG				N/A		
39 E		+	+				MEA MSCD > Y		
40 A		+	+				MEA MSCD > Y		
40 B		+	+				MEA MSCD > Y		
40 C		+	+				MEA MSCD > Y		
40 D		NG	NG				N/A		
40 E		+	+				MEA MSCD > Y		

ANALYST(S) Haydee B Romero

Key: Y = Pink colony M = Blackish, gray mold-like colony NG = No Growth

GENERAL CONTINUATION SHEET	PRODUCT Methylpred.AC(PF) 80 MG/ML Injectable	SAMPLE NO. 764940

Results from Subculture of SCD Medium on agar plates

N/A=Not Applicable

SUB #	Agar used 10/22/12 11/2/12			N/A Microscopic examination from			Colony Morphology	Subculture on	Biochemical identification
10/19/12	MAC	MEA	mSCD	MAC	MEA	mSCD	N/A	N/A	N/A
Blank Control	NG	NG	NG						
N/A									
QA:									
MAC 284-12									
MEA 283-12									
mSCD 281-12									
Chlortetracycline 242-12									

ANALYST(S) Hayclee B Romero

PAGE 3 OF 3 PAGES

Key: Y = Pink colony M = blackish, gray mold-like colony NG = no growth

NRL.MSB.NECC

Electronic Version of 431A

FDA_E00277961

ATTACHMENT A

Sample # 764940
10/9/12

From Direct inoculation of Product into
MEA plate

36B

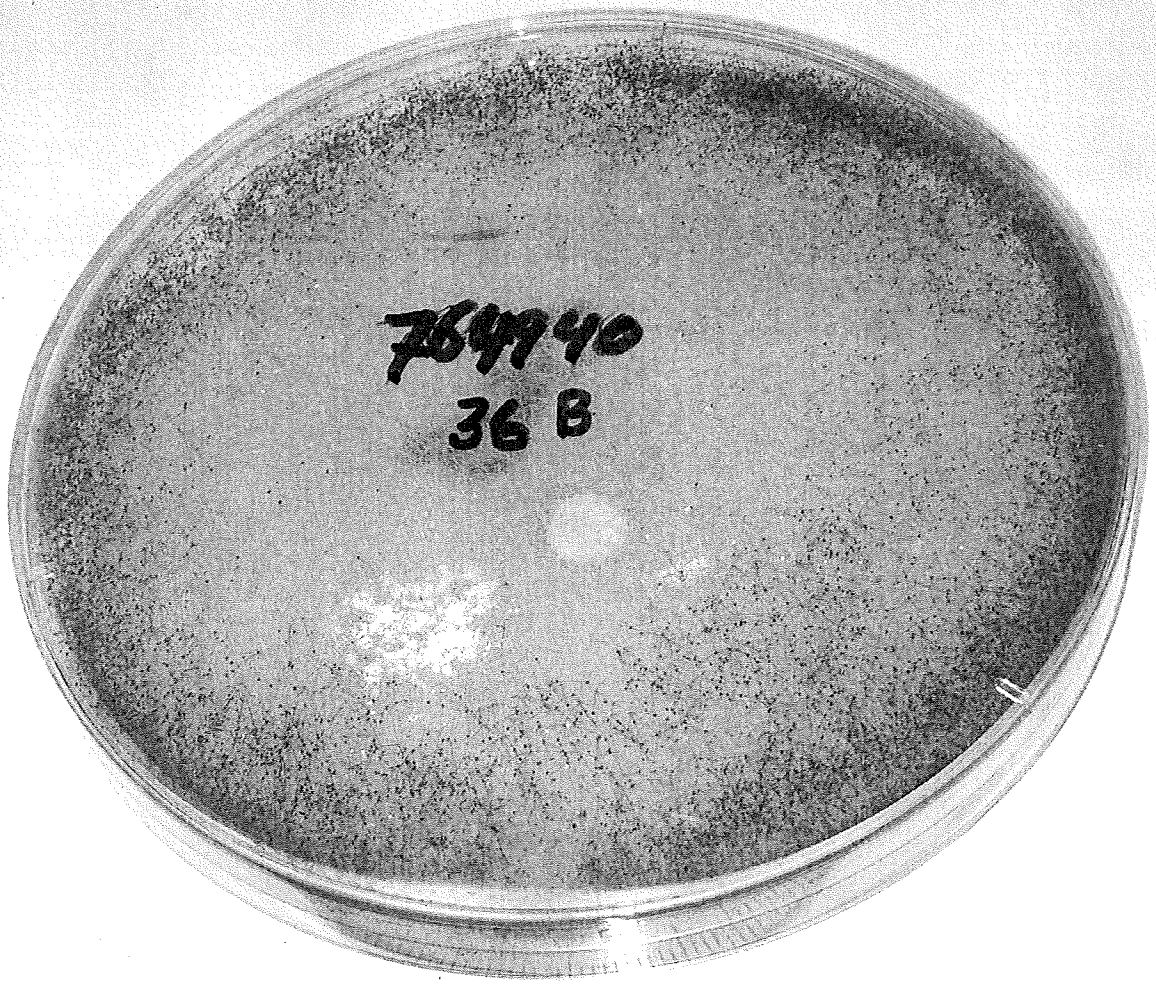
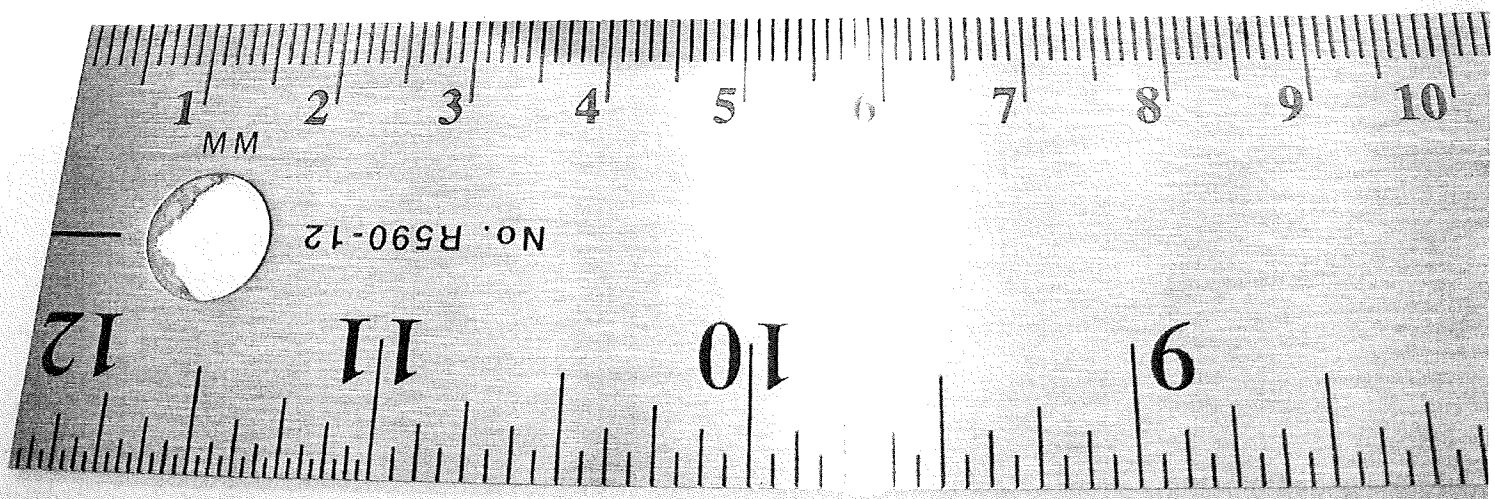


Photo taken by Jessica Brand - Sourcing 10/9/12



ATTACHMENT B

From Direct inoculation of Product onto MEA plate

Sample# 764940
Date: 10/9/12
HR
37D

PHOTO TAKEN BY: [signature] DOR 10/9/12

Photo taken by Jessica Brewer-Jacomino 10/9/12

Sample# 764940
Date: 10/9/12
HR
37D

ATTACHMENT C

Photo/copy of microscopic examination of gray colony

Magnification 100x

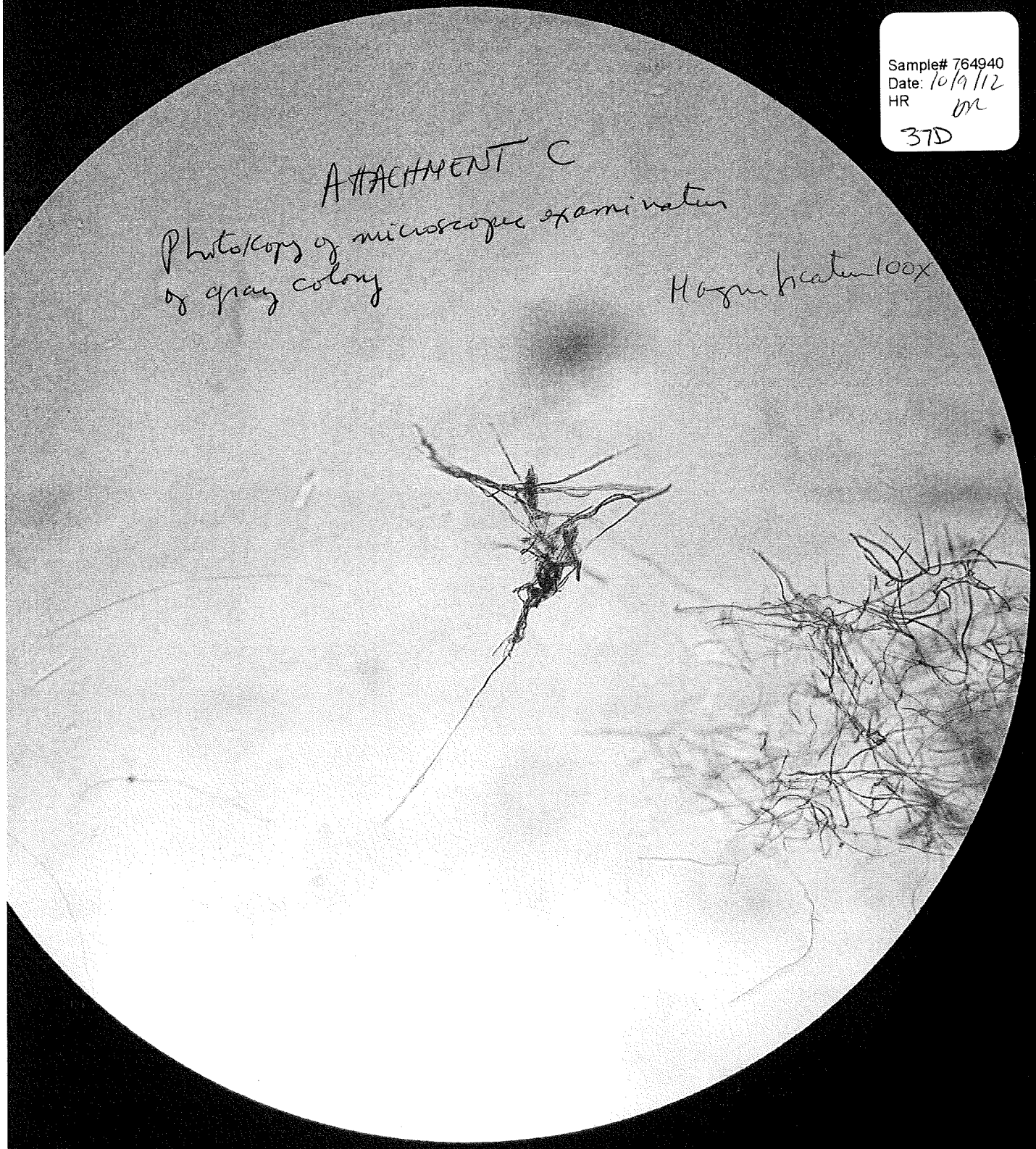


PHOTO TAKEN BY Daniel J O'Reilly 10/9/12

ATTACHMENT D

Sample# 764940
Date: 10/9/12
HR
37D

Photocopy of microscopy examination of Pink colony
Magnification 1000X

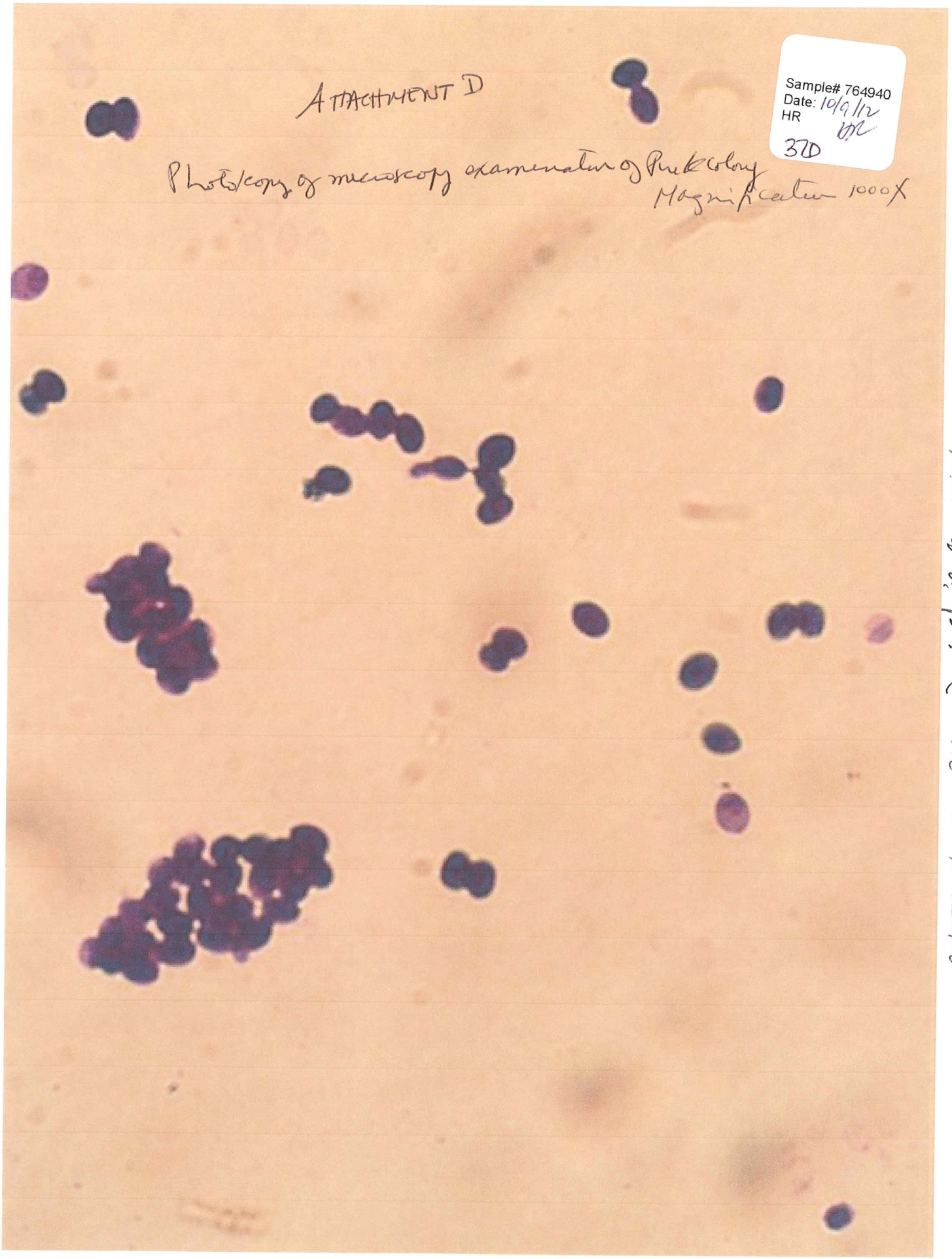


PHOTO TAKEN BY Daniel J. Kelly 10/9/12

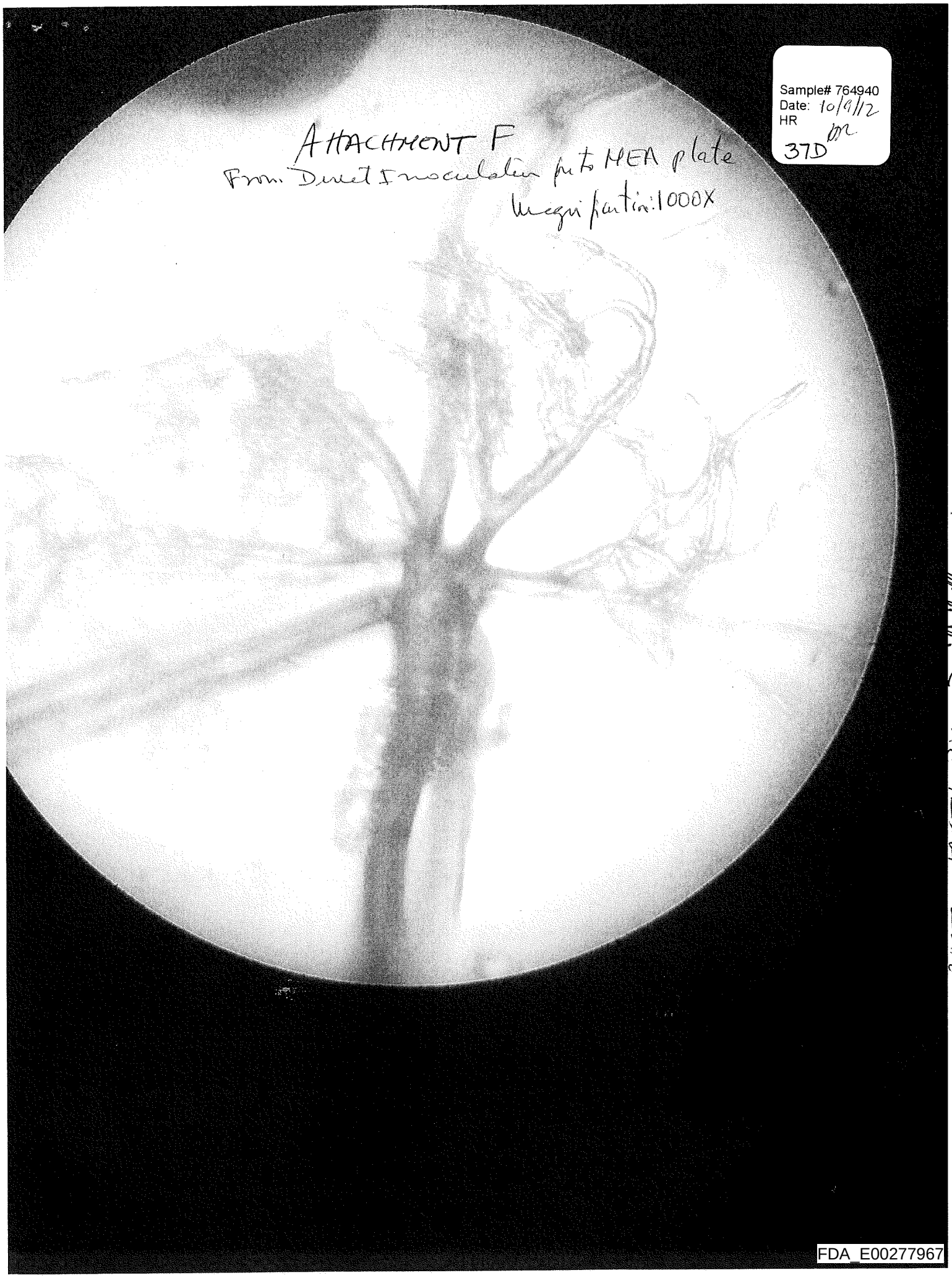
ATTACHMENT E

Photo/copy of microscopic examination of pink colony

magnification 1000 X

Sample# 764940
Date: 10/9/12
HR
370

PHOTO TAKEN BY Daniel J. Stilly 10/9/12


Sample# 764940
Date: 10/9/12
HR
37D
ATTACHMENT F
From Direct Inoculation into MEA plate
Magnification: 1000X
PHOTO TAKEN BY Daniel Phillips 10/9/12

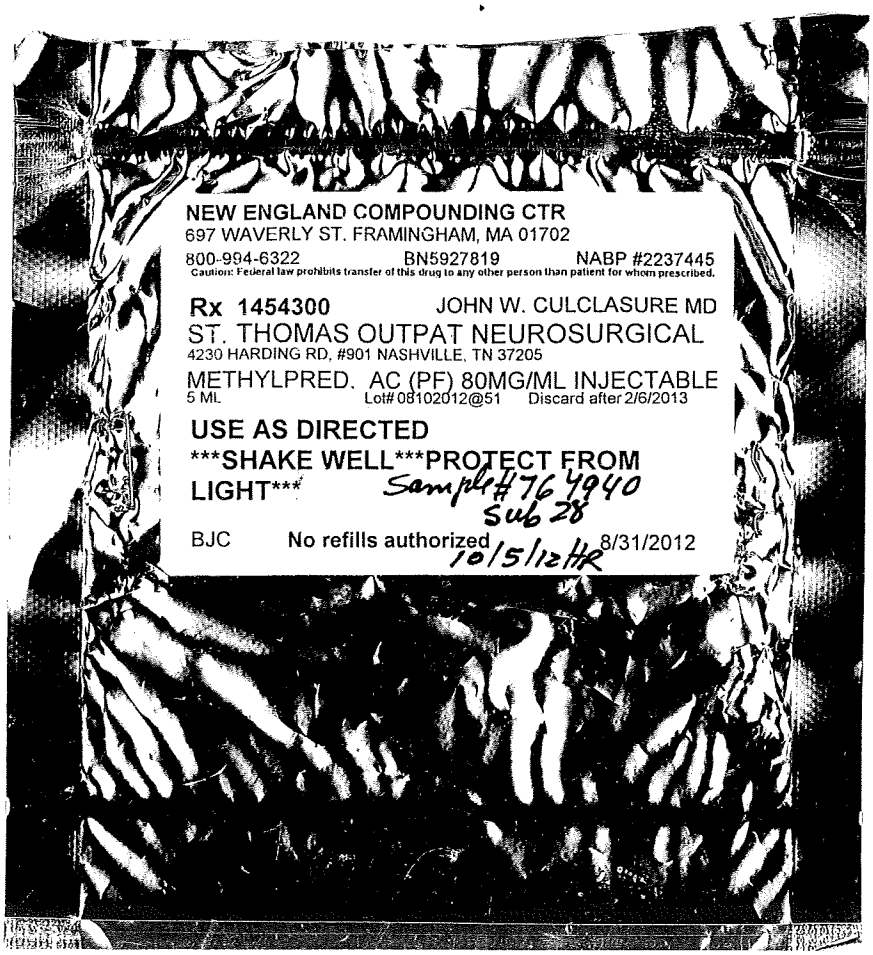
Product Unit Label

Sample #764940
10/5/12 HR

Label removed from Vial

METHYLPRED. AC (PF) 80MG/ML INJECTA
Lot#08102012@51 Discard after 2/6/2013
SHAKE WELL***SDV***
1 ML 764940 10/5 HR BCC

Label attached to foil bag



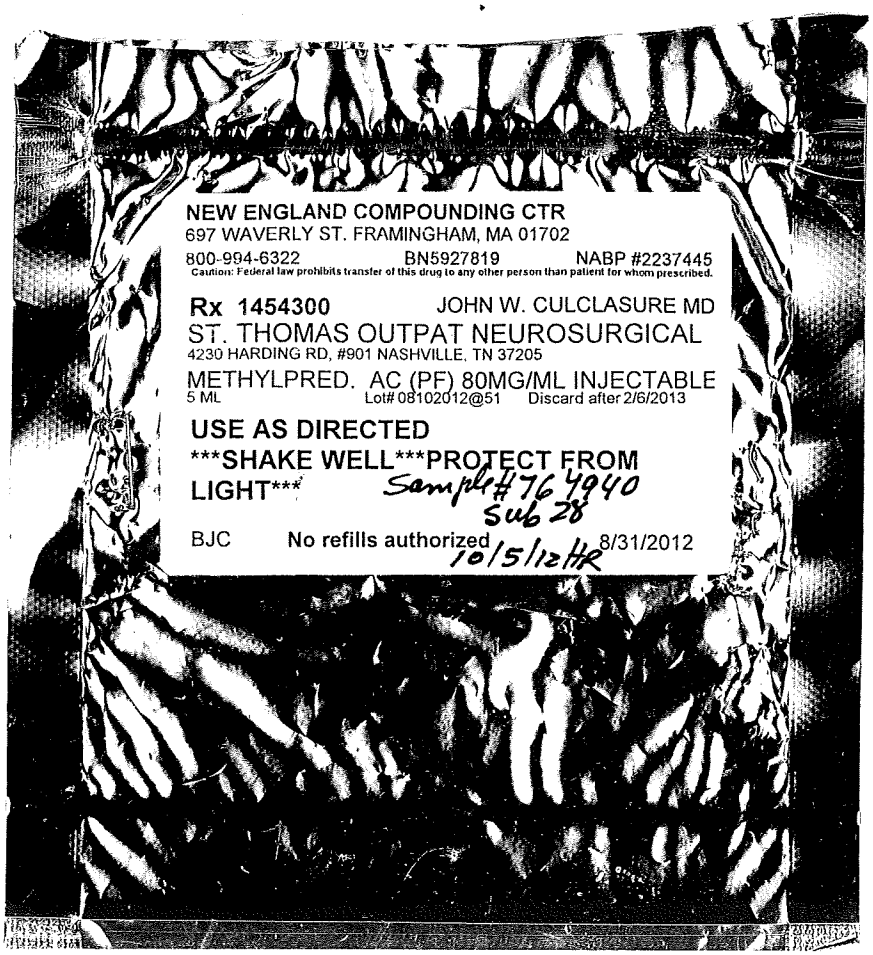
Product Unit Label

Sample #764940
10/5/12 HR

Label removed from Vial

METHYLPRED. AC (PF) 80MG/ML INJECTA
Lot#08102012@51 Discard after 2/6/2013
SHAKE WELL***SDV***
1 ML 764940 10/5 HR BCC

Label attached to foil bag



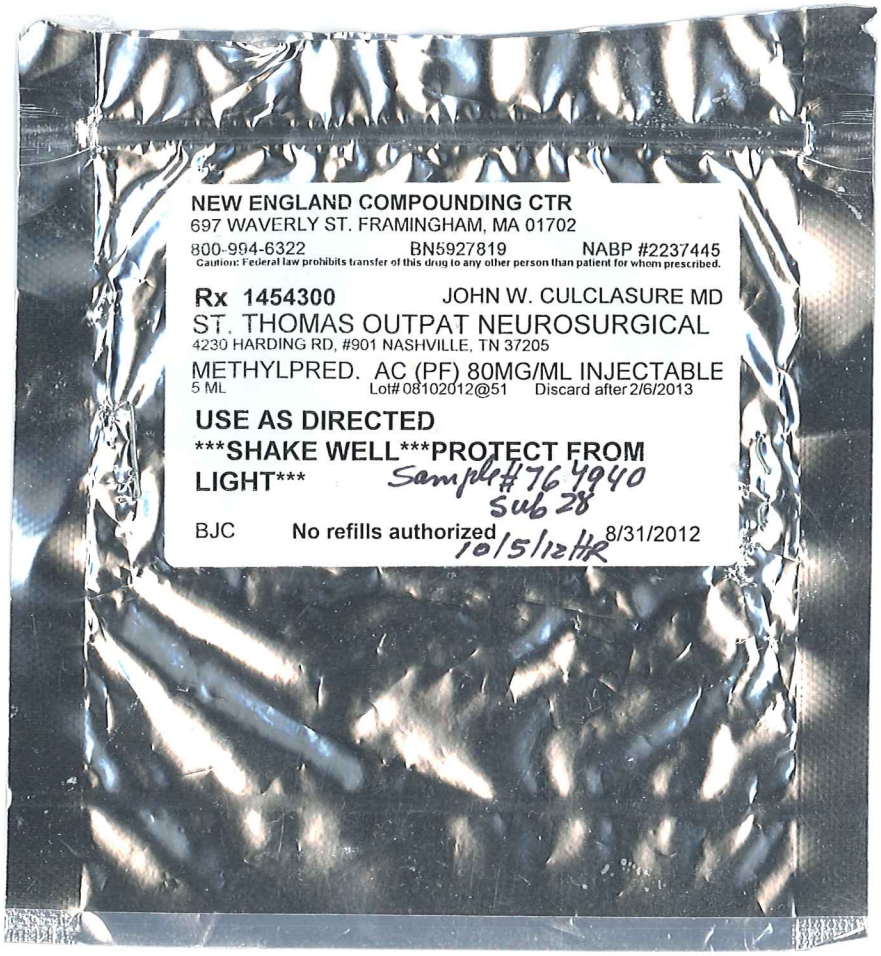
Product Unit Label

Sample # 764940
10/5/12 HR

Label removed from Vial

METHYLPRED. AC (PF) 80MG/ML INJECTA
Lot#08102012@51 Discard after 2/6/2013
SHAKE WELL***SDV***
1 ML 764940 10/5 HR BCC

Label attached to foil bag



FDA_E00277970

Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 764940 13206132

This is an accurate reproduction of the original electronic record as of 12/10/2012

Flag	Flag Remarks

Episode Number	Origin	Basis	Sample Type	FIS Smpl Num	Status
	Domestic	Other-Compln	Official	13206132	Completed

FEI	Date Collected	Product Code	Responsible Firm	PAC	Hours
3003623877	10/02/2012	64LDK45	Manufacturer	56R814	11

Compliance Num	Country of Origin
	United States

Related Smpl Num	Position Class	Sampling District	NDC Number	Permit Number	Storage Rqrmnt.
	INV	NOL-DO			Ambient

Dealer is Consumer	Crx/DEA Schedule	Recall Num	Consumer Compl. Num	Brand Name
No				NECC

Product Description
Methylprednisolone Acetate 80mg/ml packaged in 1ml clear glass vials. (Cont in Remarks)

Product Label
See continuation.

Reason for Collection	MFG Codes	Expiration Date
Collected during investigation of Aspergillus Meningitis outbreak. Analyze for sterility (presence of Aspergillus) and chemical composition.	"08102012@51"	2/6/2013

Firm Legal Name	Address	Type of Firm	Firm FEI	FCE
St. Thomas Hospital	4220 Harding Pike Nashville, TN 37205-2005 US	Dealer	1000524946	
New England Compounding Center	697 Waverly St Framingham, MA 01702-8589 US	Manufacturer	3003623877	

Size of Lot	Est. Value	Rcpt Type	Carrier Name	Date Shipped
39 individual-1ml vials and 58-5 packs of 1ml vials		FDA484		

Description of Sample
Sample consists of 27 individual 1ml vials and 42-5 packs of vials.

Method of Collection
See continuation.

How Prepared
See continuation.

Collector's Identification on Package and/or Label
"764940 10/02/12 MHK" Subs 1-69

Collector's Identification on Seal
"764940 10/02/2012 Marshall H. Kinsey"

Sample Delivered To	Date Delivered	Orig C/R & Records To
UPS	10/02/2012	NOL-DO

Lab w/Split Sample	Lab
0	NRL

Document Number	Document Date	Document Type	Document Remarks
	10/02/2012	Other	Photographs of product labeling were taken.

Remarks

FDA_E00277971

Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 764940

This is an accurate reproduction of the original electronic record as of 12/10/2012

See continuation.

Payment Amount	Payment Method	704(d) Sample	702(b) Portion	Collector's Name
$0.00	No Charge	No	No	Marshall H Kinsey

Name of Signer	Date & Time of Signature	Meaning
Marshall H Kinsey	10/10/2012 10:24 AM ET	Collector

FDA_E00277972

Continuation:

Product Label
1 ml vials are labeled in part, "***METHYLPRED. AC (PF) 80MG/ML INJECTA Lot#08102012@51***1 ML***necc***".

The foil packages are labeled in part, "NEW ENGLAND COMPOUNDING CTR***FRAMINGHAM, MA***Rx 1454300 JOHN W. CULCLASURE, MD 4230 HARDING RD. #901 NASHVILLE, TN***METHYLPRED. AC (PF) 80/MG INJECTABLE 5ML Lot#08102012@51***"

Bubble wrap bags are labeled in part, "***Total number of VIALS in this Bubble bag: *** Lot# 08102012@51".

Method of Collection
Using sterile gloves Inv. Kinsey reached into each of the four bubblewrap bags and individually removed the sample subs. Subs were placed in pre-labeled individual whirlpak bags which were held open by Inv. Smith. Whirlpaks were folded closed and placed in a clean cardboard box. Subs identified w/white self-adhesive labels & black print as shown. Subs 1-27 consist of individual vials collected from a single bubblewrap bag, subs 28-69 consist of 5-pack vials. Subs 28-41, 42-55, and 56-69 were collected from the remaining three bubblewrap bags.

How Prepared
Upon return to the office, subs were placed in a clean, unused, brown paper bag. The bag was folded closed, continuously wrapped in tape, and officially sealed as shown. Bag identified in black, handwritten ink as shown. Bag placed in a cardboard shipping container with bubblewrap and a completed FDA-525. Box prepared for shipment and taken to UPS by collector.

Remarks
(Cont from Product Description) Vials have a metal top with a white plastic lid. Vials are labeled with a white label w/ black and green print. Vials come packaged in metal foil packages, 5 per pack, which are labeled with white adhesive labels with black print. 5-pack vials come in bubblewrap bags, 20-5packs per bag. Bubblewrap bags are identified with white labels w/ black print.

A sealed FDA-525 containing a CD w/digital photos and the FDA-484 are attached to this collection report.

Approximately two thirds of products from available lots were collected. Dr. John W. Culclasure, Medical Director, stated that the hospital board had met and decided to retain 1/3 of all quarantined product for future testing by the hospital or other interested parties.

The dealer information listed in the Associated Firms section of this collection report is for the main hospital. This sample was collected from St. Thomas Outpatient Neurosurgical Center, 4230 Harding Rd. Plaza East Ste 901, Nashville, TN.